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Automated Balloon Control in Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)

C.McCarthy, I.Kanterman, F.Trauzettel, H.Jaeger, A.Goetz, B.Colvard, L.Swanstrom, P.Cantillon-Murphy

Abstract — Objective: *The goal of this work was to demonstrate technical feasibility of automated balloon pressure management during REBOA in the pre-clinical setting. Methods:* *This paper presents an intelligent balloon management device which automates the balloon inflation process, preventing the possibility of balloon over or under inflation, optimizes inflation pressure and if indicated, deflates automating partial REBOA to allow distal organ perfusion. Edwards TruWave pressure transducers are used to monitor the blood pressure proximal and distal to the balloon, as well as the internal balloon pressure. A faux PID controller, implemented on an Arduino platform, is used in a feedback control loop to allow a user defined mean arterial pressure setpoint to be reached, via a syringe driver which allows intelligent inflation and deflation of the catheter balloon. Results:* *Ex vivo testing on a vascular perfusion simulator provided the characteristic behavior of a fully occluded aorta, namely the decrease of distal pressure to zero. In vivo testing on live porcine models indicated that automated partial REBOA is achievable and by enabling partial occlusion may offer improved medical outcomes compared to manual control. Conclusion:* *Automated balloon pressure management of endovascular occlusion is feasible and can be successfully implemented without changes on current clinical workflows. Significance:* *With further development, automated balloon management may significantly improve clinical outcomes in REBOA.*

Index Terms—REBOA, balloon catheter, inflation, partial REBOA, feedback, automation, syringe, pressure

I. BACKGROUND

Non-compressible torso and junctional hemorrhage are a major cause of preventable death from trauma in both civilian and military populations [1]–[3]. These patients often present with profound hypotension and one method to emergently increase blood pressure to the heart and brain is to occlude the thoracic or proximal abdominal aorta. This traditionally was accomplished through a thoracotomy or laparotomy and aortic cross-clamp. Emergency thoracotomy (ET) is a morbid procedure that carries a significant risk of occupational injury as well [4]. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a relatively new minimally invasive medical procedure in which a balloon catheter is inserted through the femoral artery, often percutaneously, and inflated within a patient's thoracic or abdominal aorta (depending on injury

distribution) to occlude the aorta and sustain perfusion of critical organs (brain and heart). This was initially performed with off-the-shelf balloons approved for other uses, but more

recently there are commercially available solutions such as the ER-REBOA catheter (Prytime Medical Devices Inc., Boerne, TX). This results in the same beneficial physiologic changes as ET, without the morbidity of a large chest or abdomen incision. Additionally, due to its minimal invasiveness, REBOA may be theoretically performed in the pre-hospital setting which would allow emergency personnel to stabilize a patient at the scene of the injury [5]. While this represents a major advancement in the treatment of the critically injured patient, prolonged aortic occlusion during transport and in-hospital resuscitation may result in deleterious effects due to distal organ ischemia and ischemia-reperfusion injury once the occlusion is removed. One possible solution is partial REBOA (pREBOA). pREBOA is performed by partially deflating the occluding balloon catheter to a diameter slightly less than that of the thoracic aorta, allowing a small amount of flow distal to the balloon to perfuse the visceral organs. Ideally this would be timed so that mean-arterial pressure to the head and heart were kept at a sufficient level while releasing as much blood flow distally as possible. The result would be a sustained increase in blood pressure to the brain and heart, while diminishing the ischemic insult to the bowel, kidneys, and liver. pREBOA has been demonstrated to be effective in a porcine model of hemorrhagic shock. Pigs that underwent pREBOA had significantly less ischemic injury to visceral organs, while still meeting proximal blood pressure goals, and had improved short-term survival [6]. Two major challenges exist however in the workflow of performing pREBOA, especially in the pre-hospital setting or far forward military trauma unit. Without the aid of fluoroscopy, it is difficult to determine the level of balloon insertion and over- or under-inflation may occur. While under-inflation results in an obvious non-response to treatment, over-inflation may rupture the balloon or the patient's aorta, with catastrophic effects. Additionally, monitoring the inflation of the balloon to balance adequate proximal and distal pressures in pREBOA would be time consuming and impractical in this high-stress environment. Thus, a need exists to automate the proper

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inflation of a REBOA balloon catheter to avoid over- or under-inflation, and to dynamically inflate and deflate the balloon to maintain pREBOA.

II. METHODS

Theory

The balloon catheter is inserted through a 14 Fr introducer sheath in the right external iliac artery and the balloon is positioned with the tip in the mid-descending thoracic aorta. Fluoroscopy is used for confirmation of the level of insertion. Additional introducer sheaths are placed for hemodynamic monitoring and resuscitation (for experimental phase only) as follows: 6Fr sheath in the left carotid artery with the tip in the aortic arch (for central aortic pressure), a 6Fr sheath in the left external iliac artery with the tip in the distal abdominal aorta (for distal aortic pressure), a 9Fr sheath in the right carotid artery with the tip in the aortic arch (for controlled hemorrhage), and a 9Fr sheath in the right jugular vein for resuscitation. The intelligent balloon management system (IBMS) is connected by luer lock to the side-port of the right iliac sheath, which provides distal pressure, and the wire lumen of the balloon catheter, which provides the proximal pressure. Proximal (above the balloon) and distal (below the balloon) blood pressures, as well as internal balloon pressure (saline) are monitored continuously by the IBMS. The user then inputs their desired minimum proximal mean arterial pressure ($pMAP$) into the IBMS user interface (UI). Mean arterial pressure (MAP) is calculated using real time measurements of systolic (SP), and diastolic pressure (DP) in (1).

$$MAP = \frac{(SP + 2 * DP)}{3} \quad (1)$$

This study uses MAP rather than SP as MAP may present a better overall blood understanding of blood flow and also serves as an indicator of perfusion pressure. The user selected proximal mean arterial pressure maintained by dynamic inflation and deflation of the balloon catheter within the aorta, which is achieved by controlling a stepper motor powered syringe driver to inflate the balloon to the required set point. If complete aortic occlusion results in a supra-therapeutic blood pressure (above the set-point), the IBMS deflates the balloon which results in partial occlusion, a lower proximal blood pressure, and blood flow to organs distal to the balloon. If

complete occlusion results in a proximal blood pressure equal to or less than the set-point, the IBMS maintains full occlusion.

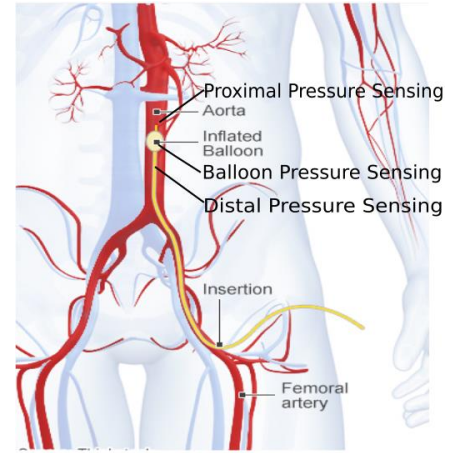


Fig.1 – Indicative IBMS implementation showing partially occluded aorta allowing distal flow.

Implementation

1. Syringe Driver

The syringe driver is based on the Open-Source Syringe Pump by Bas Wijnen, et al [7]. It is comprised of 3D printed and mechanical parts that are assembled by hand. The original parts, (gray), are made of polylactic acid. After assembly, modifications are made to the Body Holder parts, in order to fit a 60 mL/cc syringe. These modified parts (white) are made with acrylonitrile butadiene styrene. The fully assembled syringe driver is displayed in Figure 2.

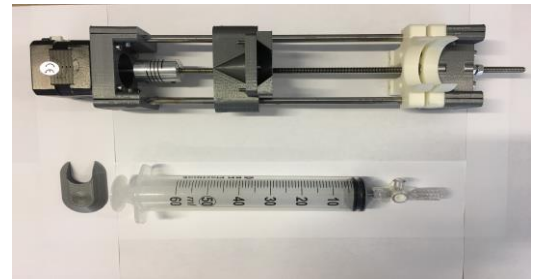


Fig.2 - Fully assembled 3D syringe driver w/ motor with 60ml syringe and locking component

2. Motor Control

The syringe driver is manipulated using a Nema17 65N stepper motor (Digikey Electronics) with a DRV8825 micro stepping motor driver (Texas Instruments Inc.) These are controlled via an Arduino UNO microcontroller. Motor movement is regulated using a faux PID controller based on an open-source configuration from Lake et al. [8]. This setup is implemented on the Arduino and is used to maintain the mean arterial pressure setpoint by inflating/deflating the balloon, in a feedback control loop as in Figure 3.

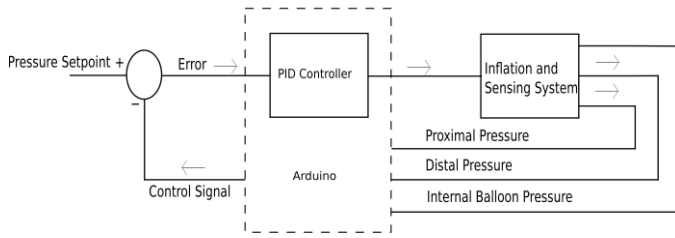


Fig.3- PID Control Diagram showing feedback signals.

Manual PID tuning was performed until acceptable step and ramp responses were achieved. The parameter values used were as indicated in Table I.

TABLE I
PID CONTROLLER PARAMETERS

Symbol	Quantity	Value
K_p	Proportional Gain	3000
K_i	Integral Gain	2.0
K_d	Derivative Gain	1.38
T_s	Sample Timing	40 ms

3. Pressure Sensing

Feedback is provided by three separate pressure transducers (TruWave single adult pressure transducers, Edwards Lifesciences Corp.) which monitor pressure proximal to, distal to, and within the balloon. These sensors are inline fluid sensors designed for invasive blood pressure measuring. One valve is attached to the fluid line which is to be measured, with the second valve connected to a pressurized saline supply. Sensor specifications are given in Table II [9]. Initial *ex vivo* testing using MPX2100 inline pressure sensors (Freescale Semiconductor, Inc.) was abandoned for *in vivo* testing due to poor noise performance.

TABLE II
EDWARDS TRUWAVE PRESSURE SENSOR SPECIFICATIONS*

Specification	Value/Range
Operating Pressure Range	-50 to +300 mmHg
Operating Temperature Range	15°C to 40°C
Overpressure Tolerance	-500 to +5000 mmHg
Sensitivity	5.0μV/V/mmHg

* At 6.00VDC and 25°C.

INA122 operational amplifiers were used for sensor amplification. The gain equation for the amplifiers is given by (2) where $R_G = 560\Omega$ resistors resulted in a gain value of 362 to utilize the full Arduino input range.

$$G = 5 + \frac{200k\Omega}{R_G} \quad (2)$$

The sensors were calibrated in the required operating range of pressures, using a water column to provide varying height dependent values of head pressure. These experiments were repeated three times for each sensor to characterize variance. The sensor behavior was found to be highly linear, with incidental variance, indicating high reliability (see Figure 4).

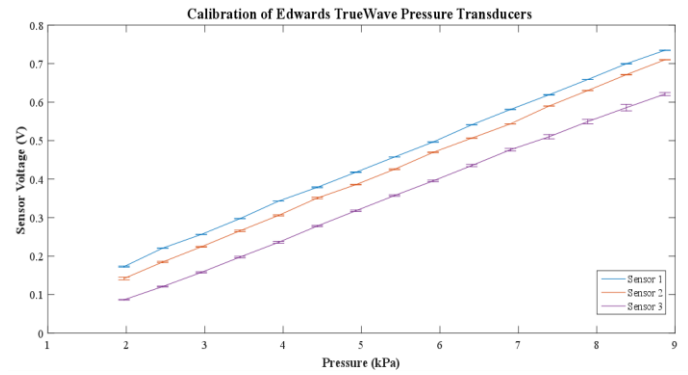


Fig.4 - Calibration graph for Edwards TrueWave Pressure Transducers. Calibrating pressures provided by water column, using head height as pressure variant

4. System Implementation

The full hardware setup for IBMS is shown in Figure 5.

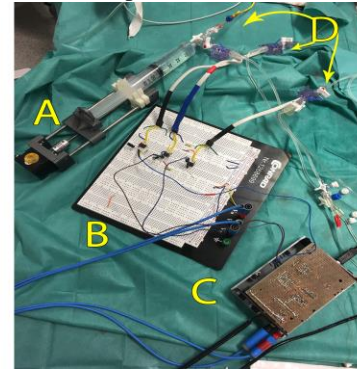


Fig.5 - Full IBMS hardware setup showing (A) the syringe driver (B) amplifier board, (C) microcontroller and (D) 3 pressure transducers.

5. Ex Vivo Testing

Ex vivo testing was performed on a bench top pulsatile vascular system simulator provided by GEPROVAS (Strasbourg, France), a research facility which analyzes explanted cardiovascular prostheses [10].

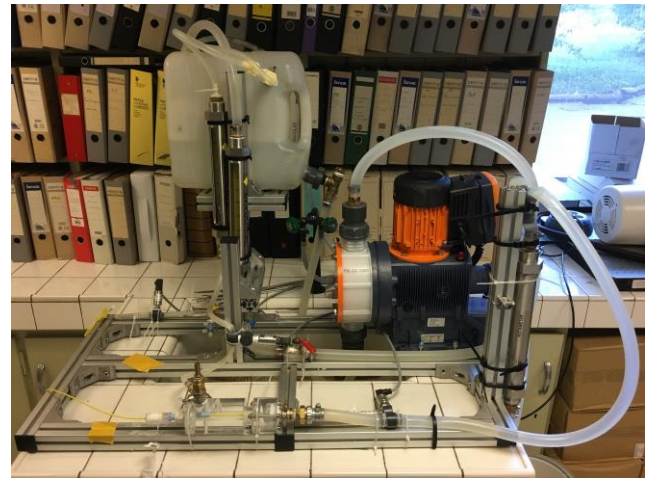


Fig.6 - The GEPROVAS vascular simulator used for *ex vivo* testing of IBMS (www.geprovas.org).

The GEPROVAS simulator (see Figure 6) allows flowrate and beats per minute to be altered, allowing multiple probable *in vivo* situations to be simulated. It is important to note that the

“aorta” in this model is hard plastic, with none of the expansion behavior witnessed in a real aorta. Of particular interest is the system response to full occlusion, which is the point at which the balloon is touching the internal walls of the flow pipe (simulated aorta). Constrained step and ramp tests (with the balloon inside the GEPROVAS aorta simulator) were performed to determine dynamic system performance, with these being compared to static unconstrained tests (balloon inflation on the open bench). The GEPROVAS system was initially set to provide 51 beats per minute, with a 71% PWM on/off stroke to replicate normal aortic conditioning during testing.

6. In Vivo Testing

Institutional Animal Ethics Committee approval was obtained in accordance with French regulations for *in vivo* non-survival porcine testing. Three female large white swine (*sus scrofa*) weighing 49-71kg were selected to undergo a controlled hemorrhage protocol based on the protocol described by Markov et. al [11] and pREBOA using the IBMS. The *in vivo* experiment had four study phases: (1) instrumentation delivery, (2) hemorrhage, (3) pREBOA, and (4) resuscitation. Physiologic parameters and hematologic laboratory values were obtained throughout the procedure. Each animal was euthanized at the conclusion of the resuscitation period. There were three animals in this, one for preliminary technology evaluation, followed by two for pre-clinical validation.

The instrumentation phase included cannulation of an ear vein, induction of IV anesthesia using Propofol and Rocuronium followed by initiation of mechanical ventilation and inhaled anesthetic with isoflurane. The bilateral common carotid arteries were then exposed along with the right internal jugular vein. Next, the bilateral external iliac arteries were exposed. One hundred units/kg of intravenous unfractionated Heparin were then administered. A 14Fr vascular sheath was then introduced into the right external iliac artery, followed by a 6Fr vascular sheath in the left external iliac artery. Next, a 9Fr sheath was introduced under fluoroscopic guidance into the right common carotid artery with the tip in the aortic arch, and a 6Fr sheath was inserted into the left common carotid artery with the tip in the aortic arch. Finally, a 9Fr sheath was introduced into the right internal jugular vein for large volume resuscitation. All sheaths were thoroughly flushed with heparinized saline to ensure patency throughout the procedure. The left carotid and external iliac artery sheaths were used to continuously monitor the proximal aortic and distal aortic pressures respectively. Monitoring the distal blood pressure via a femoral artery catheterization is standard practice in the management of major traumatic injuries once the patient has arrived to the hospital.

Controlled hemorrhage to class IV shock (40% total blood volume loss) was achieved by gradual withdrawal of blood through the right carotid vascular sheath. The rate was based on the protocol by White to simulate prehospital blood loss [12]. Based on a presumed volume of 66 ml/kg, 50% of the total

blood loss was withdrawn in 7 minutes, and 50% in the following 13 minutes. If MAP dropped below 25mmHg, hemorrhage was paused until the pressure stabilized.

Once 40% of the total blood volume was withdrawn REBOA was initiated using the IBMS to control balloon inflation and deflation. The proximal pressure sensor was connected to the wire lumen of a 32mm Coda balloon catheter (Cook Medical, Bloomington, IN). The distal pressure sensor was connected to the side-port of the 14Fr right external iliac vascular sheath. The balloon pressure sensor was connected to the balloon inflation lumen of the catheter. The Coda balloon was then inserted through the 14Fr sheath and into the descending thoracic aorta under fluoroscopic guidance. A minimum proximal aortic MAP set-point of 60mmHg (commonly used as a minimal pressure in critical care settings for the seriously injured human patient) was entered into the IBMS and the pressure feedback system was activated. The balloon was observed during inflation under fluoroscopy and intermittently throughout the 60 minutes of automated REBOA. At the 60 minute mark, the balloon was manually deflated over 2 minutes with a pause if the pressure dropped below 40mmHg. Resuscitation was begun concomitantly with normal saline boluses until the pressure was maintained above 50 mmHg. After 60 minutes of resuscitation the protocol was ended and the animals were euthanized with potassium chloride.

III. RESULTS

1. Ex Vivo Results

Ex vivo testing was performed for system characterization and tuning. Step and ramp test responses were gathered for constrained (within the dynamic flow vascular model) and unconstrained (balloon in free space) models using internal balloon pressure as the feedback signal, results of which are shown in Figure.7.

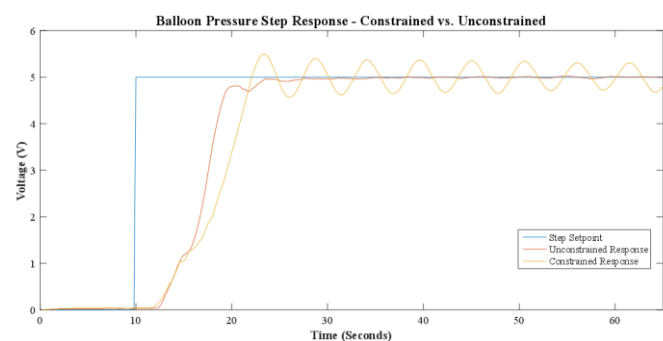


Fig.7 - Step responses for constrained and unconstrained catheter balloon pressure under IBMS control. The damped nature of the control system is visible with roughly 15 second settling time.

The unconstrained step response (red line) was shown to be strongly dampened with no overshoot. This behavior is required as over inflation of the balloon has to be avoided. Inflation time from fully deflated to the required setpoint is less than 15 seconds, and was limited by the motor stalling when being driven too hard. The constrained response was seen to have a slower settling time, and because of the dynamic pulsatile

nature of the system, some unavoidable oscillatory behavior is observed.

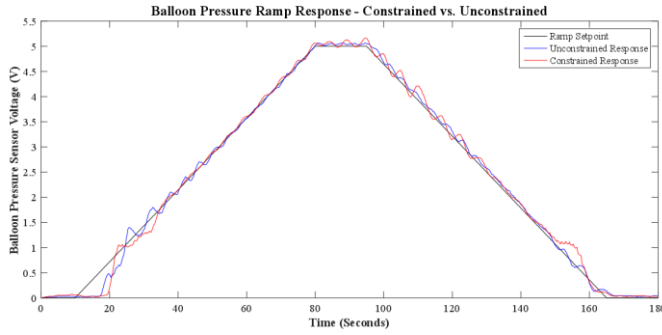


Fig.8 - Ramp responses for constrained and unconstrained catheter balloon under IBMS control. Ramp tracking is shown to be accurate with a swift response time. Some degradation is seen when deflating, which seems to be related to dynamic pulsing on a semi inflated balloon.

Ramp responses for constrained (red) and unconstrained (blue) tests are remarkably similar, shown in Figure 8. Following the initial dead band region where a certain level of inflation is required to provide a feedback signal, the control system tracks the ramp setpoint with a high degree of accuracy. Some divergence from the setpoint ramp is seen in the initial deflation of the balloon in the constrained setting, likely caused by the increased effect of the pulsing fluid flow on a partially inflated balloon. The results of testing the systems behaviour for different levels of occlusion in the GEPROVAS vascular model are shown in Figure 9.

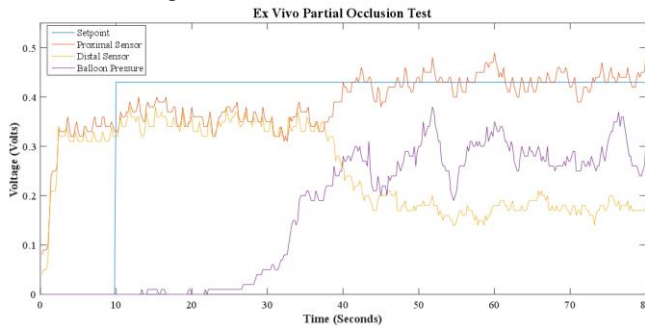


Fig.9 - Ex vivo partial occlusion testing showing the effects of partial balloon inflation on proximal and distal pressure. Distal pressure can be seen decreasing but remains relatively high.

For the *ex vivo* partial occlusion case, it is first important to note that significant distal pressure and flow can be seen when the proximal setpoint has been reached. Of particular interest is that the internal balloon pressure for a partial occlusion test lies between the levels of the proximal and distal pressures.

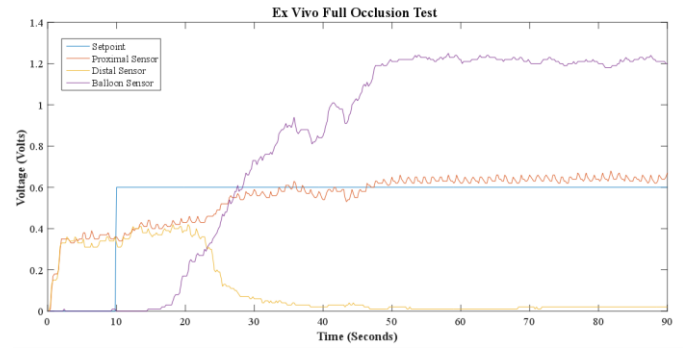


Fig.10 - Ex vivo full occlusion testing showing the decay of distal pressure to zero as distal flow decreases and the spike in balloon pressure witnessed when the balloon fully blocks the simulated "aorta".

In the above case, as the balloon inflates, the proximal pressure can be seen to rise to its physical limit, with the distal pressure decaying to zero as the flow is fully obstructed. A spike in balloon pressure can be seen around the 50 second mark, which seems to be an identifying feature of a fully occluded *ex vivo* "aorta". A number of methods for identifying full occlusion therefore present themselves, including the point at which distal pressure decays to zero, the lack of increase in proximal pressure for increases in balloon pressure and the relative lack of effect that the pulsed flow has on a fully inflated balloon.

2. In Vivo Results

What follows are the results from the second *in vivo* experiment, on a 71 kg female pig following the protocols of Section II.6. A large animal was chosen to provide strong pressure signals throughout the experiment.

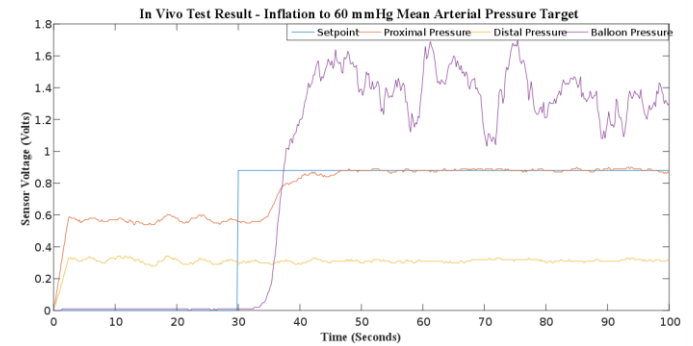


Fig.11 - In vivo inflation period, focusing on the increase in proximal pressure to the user defined setpoint of 60 mmHg. Required setpoint is reached within 20 seconds, with the aorta remaining partially occluded.

Figure 11 shows the initial inflation period to the required mean arterial setpoint of 60 mmHg, approximated by a mean proximal balloon pressure of 85 mmHg ($\sim 0.9V$). The required setpoint was achieved within 20 seconds of initial inflation. Figure 11 corresponds to a partially occluded aorta. The noise associated with the internal balloon pressure signal is discussed in Section VI. In this study, fluoroscopy imaging of the aorta was used for confirmation when placing the uninflated balloon, and again following inflation of the balloon to the required setpoint, to confirm location. These images are shown in Figure 12.

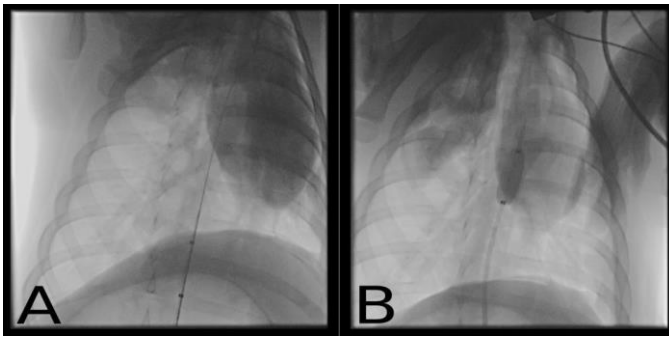


Fig.12 - Fluoroscopy images showing the initial placement of the deflated balloon. Right hand image shows partially inflated balloon, inflated by IBMS, which allows distal flow to perfuse through the body.

The balloon was filled with a saline solution including a contrast media (Omnipaque, GE Healthcare Inc.), allowing it to be seen more clearly on the images. Figure 12(b) shows a partially occluded aorta with sufficient distal flow to prevent the negative effects which are associated with full occlusion.

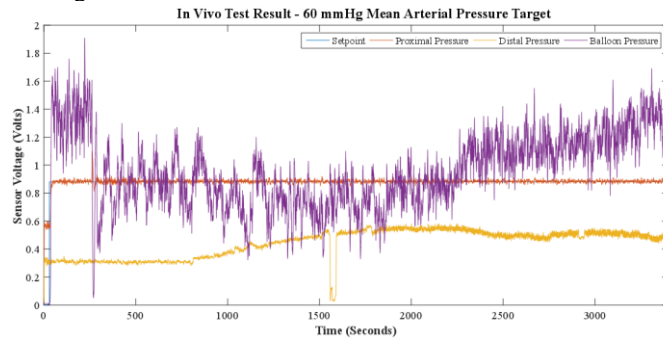


Fig.13 - Full in vivo data collection over 60 minutes, showing the IBMS reaction to animal self-regulation of blood pressure.

The experiment continued for 60 minutes of partial REBOA. The sudden dip seen in the distal waveform (yellow) was caused by the erroneous closing of a flow valve. Of importance here is the reactive inflation and deflation of the balloon as it worked to maintain the required setpoint. Allowing for the noise on the internal balloon pressure signal, it can be seen that following initial inflation, the balloon deflated significantly as the animal self-regulated its blood pressure due to the partial occlusion of its aorta. As the experiment continued, the balloon again automatically inflated to maintain the proximal pressure value, as the animal began to suffer the effects of prolonged hemorrhagic shock. This is confirmed by a slight decrease in distal pressure, beginning around 2400 seconds. This behavior is indicative of the dynamic situation in which the IBMS device is required to operate. The temporary drop in distal pressure at 1580 seconds in Figure 13 was due to inadvertent valve closure by an operator.

IV. DISCUSSION

This study shows that the Intelligent Balloon Management System can recognize a fully occluded aorta, ensuring that over inflation of an occluding balloon can be avoided. This was adequately characterized in the pre-clinical setting and demonstrated *in vivo*. Fully occlusive REBOA or partially occlusive pREBOA can be accurately and automatically maintained for a prolonged period of time. Controlled inflation

and deflation cycles are performed using an open source syringe driver which can be easily replicated. The initial sensor used for the internal balloon pressure measurement was the MPX2100 sensor, which was subsequently replaced by the Edwards TruWave pressure transducers for *in vivo* testing. The MPX sensors were significantly more prone to noise effects which accounts for the unexpectedly noisy waveforms shown in Figures 9 and 10 for *ex vivo* testing. The Edwards TruWave pressure transducers require in-line pressurized saline supply (saline bag pressurized to 300 mmHg) to function correctly, which may not be available in the pre-hospital setting. Issues surrounding accurate calibration for mean arterial pressure reading also require further attention, as well as an optimally packaged hardware setup to minimize risk of electromagnetic interference from the stepper motor affecting the system pressure readings. Also, the effect of saline/contrast agent admixture viscosity on set-point tracking response could be addressed at calibration by specifying the preferred contrast/saline ratio for use. Future system characterization should investigate whether the user interface should facilitate specification of mean arterial (or systolic) pressure goal, or percentage occlusion (90% occlusion being almost fully occluded, 50 % occlusion allowing significant distal blood flow). Even in the absence of a wire-guide, minimal distal migration of the balloon was observed during full and partial inflation. Migration was also inhibited by firmly fixing the catheter at the groin. The 32mm balloon and 12Fr sheath combination used in this study represents a common approach in current REBOA practice although future work might seek to validate accurate distal pressure measurement with a smaller sheath, ideally one which facilitates manual compression on removal. While the current study demonstrated adequate response with the Cook Coda balloon, future investigations may benefit from the development of a customized pREBOA specific balloon catheter to improve the ease and speed with which the system can be set up and powered on. Any final balloon design should incorporate integrated proximal and balloon pressure monitoring within the balloon catheter, and the blood pressure may be monitored from the femoral introducer sheath. Such a system may enable the surgeon to program either systolic or MAP set-points during treatment. In the current protocol, the balloon was placed above the diaphragm, and below the aortic arch, as validated by fluoroscopic imaging. Future work may alleviate or eliminate dependence on radiological imaging through the use of electromagnetic tracking [13] or ultrasound [14]. Future work is also required to improve the accuracy of pressure readings, the mobility and usability of the device and to eliminate fluoroscopy as a confirmation method. Finally, while the current study demonstrated adequate response with the Cook Coda balloon, future investigations may benefit from the development of a customized pREBOA specific balloon catheter to improve the ease and speed with which the system can be set up and powered on. Any final balloon design should incorporate integrated proximal and balloon pressure monitoring within the balloon catheter, and the blood pressure may be monitored from the femoral introducer sheath. Such a system may enable the

surgeon to program either systolic or MAP set-points during treatment. In the current protocol, the balloon was placed above the diaphragm, and below the aortic arch, as validated by fluoroscopic imaging.

V. CONCLUSION

This is the first report of a fully automated system for controlling partial and complete endovascular occlusion of the aorta. The intelligent balloon management system maintained a user defined proximal arterial pressure for partial REBOA and can recognise a fully occluded aorta in-vivo, preventing over inflation of the balloon. The feasibility of automated partial REBOA is clinically significant as it may decrease patient recovery time by continuing blood circulation to the lower limbs while maintaining adequate pressure to the brain. Additional pre-clinical validation studies are required to confirm safety and reliability. However, the study provides compelling validation of the proof-of-concept prototype.

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